510(k) Summary

MAY 18 2011

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Device Information

Trade Name: Mitra-Lift Set

Device: Ring, Annuloplasty

Regulation Description: Annuloplasty Ring

Product Code: KRH

Regulation Number: 870.3800

Device Class: Class II

Submission Types: 510(K) Submission

General Description

Mitra-Lift Set is set of devices for mitral annuloplasty. This set consists of Mitra-Lift (implant device for mitral annuloplasty), and its accessories (Sizers and holders). The main device (Mitra-Lift series) is supplied sterile and intended for single use only. Mitra-Lift series is constructed of polyester textile materials and provided as the various sizes. It is intended to be used with its accessories, Mitral Sizer and Holder Handle.

Indication for Use

The Mitra-Lift is indicated as reinforcement for repair of the human cardiac mitral and tricuspid valves damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring. The annuloplasty ring should be used only in cases where visual inspection confirms that the valve is repairable and does not require replacement.

Predicate Devices:

The subject device is substantially equivalent to the following predicate devices:

- Simplici-T Annuloplasty System (K052970) manufactured by Medtronic Heart Valves (Medtronic).

Performance Data

Non-clinical laboratory testing was performed demonstration that the device complied with the USP Monographs and with the EP Monographs for Absorbable surgical sutures.

The results of biocompatibility testing support that the materials used in the manufacture of the Mitra-Lift are non-toxic, non-hemolytic, and non-pyrogenic. All testing was conducted under Good Laboratory Practices per 21 CFR Part 58. Mechanical Integrity testing for the COMVAR Set (including Mitra-Lift Set) includes suture retention testing which demonstrated that the design provided for a more than adequate retention force as compared to the predicate device. Testing demonstrated that the Mitra-Lift Set is substantially equivalent to the predicate device for repair of the mitral or tricuspid valve.

Comparison to Predicate Devices

Testing and other comparisons have established that the subject of Mitra-Lift Set is substantially equivalent in design, materials, indications and intended use, packaging, labeling, and performance to other predicate devices of the type currently marketed in the U.S.

Conclusion

The Mitra-Lift, subject of this submission, constitutes a safe, reliable and effective medical device, meeting all the declared requirements of its intended use. Device presents no adverse health effects or safety risks to patients when used as intended. The Mitra-Lift has the same intended use and fundamental scientific technology as its predicate devices Simplici-T Annuloplasty System (K052970) manufactured by Medtronic Heart Valves (Medtronic). Therefore, Mitra-Lift and its predicate devices are believed to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 18 2011

Sciencity Co.,Ltd.
c/o Ms. Joyce Bang
Kodent, Inc.
325 N. Puente St. Unit B
Brea, California 92821

Re: K103812
Mitra-Lift Set
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II (two)
Product Code: KRH
Dated: May 9, 2011
Received: May 12, 2011

Dear Ms. Bang:

This letter corrects our substantially equivalent letter of May 18, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

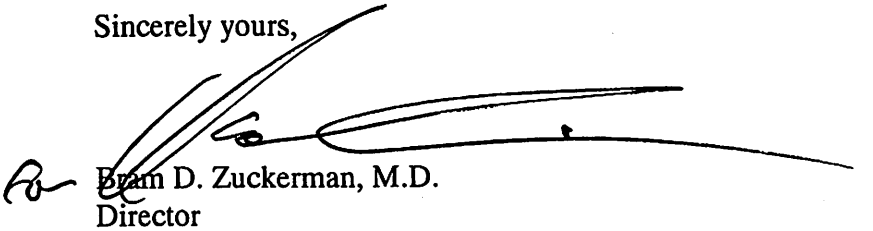
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K103812

Device Name: Mitra-Lift Set

Indication for Use:

The Mitra-Lift Set is indicated as reinforcement for repair of the human mitral valves damaged by acquired or congenital disease, or as a replacement for a previously implanted annuloplasty ring. The annuloplasty ring should be used only in cases where visual inspection confirms that the valve is repairable and does not require replacement.

Prescription Use _____X_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103812